

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION**

Children's Health Defense, *et al.*,

Plaintiffs,

v.

Food & Drug Administration, *et al.*,

Defendants.

Case No. 6:22-cv-00093-ADA-DTG

Declaration of Suzann Burk in Support of Defendants' Motion to Dismiss

I, Suzann Burk, declare as follows:

1. I am the Director of the Division of Disclosure and Oversight Management ("DDOM"), Office of Communication Outreach and Development, Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland.

2. As the Director of DDOM, I have overall responsibility for the disclosure of documents officially maintained by CBER, the center in FDA that regulates biologic products such as blood, vaccines, gene therapy, and human cells, tissues, and cellular and tissue-based products. I have been the Director of DDOM since June 24, 2018. Prior to that date, I was the Team Lead of the Electronic Disclosure Team in DDOM for approximately nine and one-half years. Prior to that, I was a member of the Congressional and Oversight Branch in DDOM for two years and a member of the Access Litigation and Freedom of Information Branch in DDOM for four years.

3. In my capacity as Director of DDOM I have access to official CBER documents. I am responsible for disclosing documents in litigation on behalf of CBER.

4. I submit this declaration in support of Defendants' Motion to Dismiss Plaintiffs' Complaint. The statements made in this declaration are based on my personal knowledge and official records available to me in my official capacity.

5. Attached hereto are copies of the following documents:

Exhibit	Document	Date
Exhibit 1	Letter of Authorization from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, FDA, to Pfizer Inc.	Jan. 3, 2022 (reissuance)
Exhibit 2	Fact Sheet for Recipients and Caregivers for Use in Individuals 5-11 years of age	Jan. 3, 2022 (revised)

6. I certify that each document listed in Paragraph 5 was the current effective version as of January 24, 2022, and was publicly available on FDA's website, <https://www.fda.gov>, as of that date.

7. I declare under penalty of perjury that the foregoing Exhibits 1 and 2 and the facts contained in this declaration are true and correct pursuant to 28 U.S.C. § 1746.

Suzann H. Burk -S
Digitally signed by Suzann H. Burk
 -S
 Date: 2022.04.21 08:16:23 -04'00'

SUZANN BURK
 Division Director
 Office of Communication,
 Division of Disclosure and Oversight Management, Outreach and Development
 Center for Biologics Evaluation and Research
 Food and Drug Administration
 U.S. Department of Health and Human Services

Executed on April 21, 2022